

REMARKS

Claims 1-49 are pending. Claims 22-35 are under examination. Claims 22, 24 and 30 have been amended. Support for the amendments can be found throughout the specification and the claims as filed. In particular, support for the amendment to recite measuring a data element for each of n components can be found, for example, on page 17, lines 11-23, and page 62, lines 23-26. Support for the amendment to recite three components and n-dimensional space can be found, for example, on page 5, lines 19-29 and Figure 1; page 17, line 25, to page 18, line 18; and page 37, lines 11-24. Accordingly, these amendments do not raise an issue of new matter and entry thereof is respectfully requested.

Rejection Under 35 U.S.C. § 101

The rejection of claims 22-35 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter is respectfully traversed. Applicants respectfully submit that the claimed methods are directed to statutory subject matter.

In the Office Action, the Office states that a process is statutory subject matter if (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing, referencing *In re Bilski*, 88 USPQ2d 1385 Fed. Cir. 2008. Applicants respectfully disagree with the assertion in the Office Action and maintain that the claimed methods are directed to statutory subject matter. Applicants further disagree with the assertion in the Office Action that the phrase “physically perturbing a component” is not considered a transformation of an article to a different state or thing. As taught in the specification (page 30, lines 9-22):

As used herein, the term “perturbed condition” when used in reference to a biochemical system, is intended to mean an alteration of a biochemical state or circumstances imposed on a biochemical system compared to a reference or normal state or circumstances of the biochemical system. A perturbation, to effect a perturbed condition, can include, for example, any physical modification or treatment of the biochemical system as well as exposure to any stimulus. Therefore, a perturbation can include, for example, genetic alterations, contact with macromolecules, compounds, agents and drugs, and exposure to changes in and environmental stimuli or procedural manipulations of a biochemical system.

Based on the teachings in the specification and what would have been understood by those skilled in the art as to the meaning of the phrase “physically perturbing a component,” Applicants respectfully submit that there is no basis for interpreting the phrase “physically perturbing a component” as not involving transformation to a different state or thing as asserted in the Office Action. Moreover, each of independent claims 22, 24 and 30 has been amended to recite the phrase “measuring a data element for each of n components” of a perturbed biochemical system. Therefore, it is respectfully submitted that the claimed methods recite one or more steps that are not “only mental steps.”

Applicants respectfully submit that the claimed methods are directed to statutory subject matter. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejection Under 35 U.S.C. § 102

The rejection of claims 22-35 under 35 U.S.C. § 102(b) as allegedly anticipated by Stoughton et al., U.S. Patent No. 6,132,969, is respectfully traversed. Applicants respectfully maintain, for the reasons of record, that the claimed methods are novel over Stoughton et al.

Independent claim 22, as amended, is directed to a method for assigning a cellular function to a component of a biochemical system by (a) physically perturbing a component of a network in a biochemical system; (b) measuring a data element for each of n components of the perturbed biochemical system, wherein n is three or more; (c) determining a multidimensional coordinate point in n-dimensional space representative of the data elements for each of the three or more measured components of the perturbed biochemical system, the multidimensional coordinate point comprising values for the data elements for each of the n measured components, wherein n corresponds to the number of measured biochemical components within the perturbed biochemical system; (d) comparing the multidimensional coordinate point to a reference data element region; (e) determining if the multidimensional coordinate point is within or outside the reference data element region, and (f) providing an output to a user of the determination in step (e), wherein a multidimensional coordinate point outside of the reference data element region indicates that the component is linked to the perturbed biochemical network, and is thereby assigned a cellular function of the network.

Independent claim 24, as amended, is directed to a method for assigning a cellular function to a component of a biochemical system by (a) measuring a data element for each of n components of a physically perturbed biochemical system, wherein n is three or more; (b) determining a multidimensional coordinate point in n -dimensional space representative of data elements for each of the three or more measured components in a biochemical network of the physically perturbed biochemical system, the multidimensional coordinate point comprising values for the data elements for each of the n measured components, wherein n corresponds to the number of measured biochemical components within the perturbed biochemical system; (c) comparing the multidimensional coordinate point to a network-associated reference expression region of the set of components; (d) determining if the multidimensional coordinate point is outside of the network-associated reference expression region, and (e) providing an output to a user of the determination in step (d), wherein a multidimensional coordinate point outside of the network-associated reference expression region indicates a perturbed state of the network, the component being linked to the perturbed network and thereby being assigned a cellular function of the network.

Independent claim 30, as amended, is directed to a method for assigning a cellular function to a component of a biochemical system by (a) measuring a data element for each of n components of a physically perturbed biochemical system, wherein n is three or more; (b) determining a multidimensional coordinate point in n -dimensional space representative of data elements of the three or more measured components in a biochemical pathway of the physically perturbed biochemical system, the multidimensional coordinate point comprising values for the data elements for each of the n measured components, wherein n corresponds to the number of measured biochemical components within the perturbed biochemical system; (c) comparing the multidimensional coordinate point to a pathway-associated reference expression region of the set of components; (d) determining if the multidimensional coordinate point is outside of the pathway-associated reference expression region, and (e) providing an output to a user of the determination in step (d), wherein a multidimensional coordinate point outside of the pathway-associated reference expression region indicates a perturbed state of the pathway, the component being linked to the perturbed pathway and thereby being assigned a cellular function of the pathway.

Applicants respectfully maintain, for the reasons of record, that Stoughton et al. does not teach the claimed methods, in which a multidimensional coordinate point in n-dimensional space representative of data elements for each of three or more measured components of a perturbed biochemical system is determined. As discussed previously on the record, Applicants respectfully disagree with the assertion in the Office Action that “microarrays inherently involve mRNA locations containing x and y dimensions (multidimensional coordinate points) representative of a data element of two or more components of a physically perturbed system comprising values for a data element for each of n components (i.e. measurements of drug exposure and levels of perturbation in a 2-dimensional microarray space) corresponding to the number of measured components within the biochemical system.” As discussed previously on the record, the “x and y coordinates” of an array are locations of arrayed material such as mRNA on the array. Thus, the x and y coordinates of a given mRNA is clearly the position of the mRNA on the two-dimensional array. However, the physical position of an mRNA on an array clearly has no relationship to a data element, as asserted in the Office Action on page 4. As taught in the specification, a “data element” is a value or analytical representation of factual information that describes a characteristic or a physicochemical property of a component of a biochemical system (page 28, line 26, to page 29, line 2). Thus, a data element is a value representative of a characteristic or property of a component. In contrast, the x and y values relating to the position of a particular mRNA on an array has no relationship to the mRNA as being representative of a characteristic or property of the mRNA. To the contrary, the x and y values relating to the position of an mRNA on an array provide nothing more than information on the arbitrary location of the mRNA on the array, not a characteristic or property of the mRNA.

In contrast to Stoughton et al., a multidimensional coordinate point, as recited in the claims, is representative of data elements for each of three or more measured components. Furthermore, the claims explicitly recite that the multidimensional coordinate point is in n-dimensional space, where n corresponds to the number of measured biochemical components within the perturbed biochemical system. As exemplified in Figure 1, which shows multidimensional coordinate points in three dimensions for three components, each of the multidimensional coordinate points comprises values for the data element for each of the n (three) components in three-dimensional space. In contrast and as discussed above, the x and y

coordinates of an mRNA on an array, as asserted in the Office Action to be a multidimensional coordinate point as described in Stoughton et al., clearly are arbitrary positions on a two-dimensional array but do not represent values of a characteristic or property of a component. Furthermore, the position of a given mRNA on an array relates only to that mRNA, i.e. "component." However, Stoughton et al. provides no teaching of a multidimensional coordinate point in n-dimensional space representative of data elements for each of three or more measured components, as recited in the claims. Absent such a teaching, Stoughton et al. cannot anticipate the claims.

Applicants respectfully maintain that the claimed methods are novel over Stoughton et al. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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